



MEDICAL DEVICE USE ERROR

# ROOT CAUSE ANALYSIS

Michael Wiklund  
Andrea Dwyer  
Erin Davis

Illustrations by Jonathan Kendler



# Medical Device Use Error Analysis

**James E. Houston**

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## **RISK MANAGEMENT FOR THE MEDICAL DEVICE INDUSTRY**

Dr. Akash Sharma, Ms. Vriti Gamta , Mr. Gaurav Luthra,2023-07-25 Risk Management for the Medical Device Industry A Guide based on ISO 14971 is an essential resource for professionals in the fast paced medical device industry Authored by Dr Akash Sharma Ms Vriti Gamta and Mr Gaurav Luthra experts in regulatory affairs and quality management systems this practical guide offers comprehensive insights into risk management and compliance Covering the entire risk management lifecycle it includes case studies best practices and practical examples along with discussions on integrating risk management with quality management systems and emerging technologies Equip yourself with the knowledge and tools to ensure safety and effectiveness in the global market

*Applied Human Factors in Medical Device Design* Mary Beth Privitera,2019-06-15 Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in depth descriptions of both empirical and analytical methodologies The book begins with an overview of the design control process integrating human factors as directed by AAMI TIR 59 and experienced practice It then explains each method describing why each method is important its potential impact when it s ideal to use and related challenges Also discussed are other barriers such as communication breakdowns between users and design teams This book is an excellent reference for professionals working in human factors design engineering marketing and regulation Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union EU Explains technology development and the application of human factors throughout the development process

Covers FDA and MHRA regulations Includes case examples with each method    **Using Human Factors Engineering to Improve Patient Safety** John W. Gosbee,Laura Lin Gosbee,2005 Human factors engineering HFE is concerned with understanding human characteristics and how humans interact with the world around them and applying that knowledge to

the design of systems that are safe efficient and comfortable This book describes how to use HFE tools and principles to curb preventable errors and minimize patient harm *Advances in Patient Safety* Kerm Henriksen,2005 v 1 Research findings v 2 Concepts and methodology v 3 Implementation issues v 4 Programs tools and products **NTIS Alert** ,2005 *Thesaurus of ERIC Descriptors* ,1982 **Humanizing Healthcare - Human Factors for Medical Device Design** Russell J.

Branaghan,Joseph S. O'Brian,Emily A. Hildebrand,L. Bryant Foster,2021-02-21 This book introduces human factors engineering HFE principles guidelines and design methods for medical device design It starts with an overview of physical perceptual and cognitive abilities and limitations and their implications for design This analysis produces a set of human factors principles that can be applied across many design challenges which are then applied to guidelines for designing input controls visual displays auditory displays alerts alarms warnings and human computer interaction Specific challenges and solutions for various medical device domains such as robotic surgery laparoscopic surgery artificial organs wearables continuous glucose monitors and insulin pumps and reprocessing are discussed Human factors research and design methods are provided and integrated into a human factors design lifecycle and a discussion of regulatory requirements and procedures is provided including guidance on what human factors activities should be conducted when and how they should be documented This hands on professional reference is an essential introduction and resource for students and practitioners in HFE biomedical engineering industrial design graphic design user experience design quality engineering product management and regulatory affairs Teaches readers to design medical devices that are safer more effective and less error prone Explains the role and responsibilities of regulatory agencies in medical device design Introduces analysis and research methods such as UFMEA task analysis heuristic evaluation and usability testing *Encyclopedia of Medical Devices and Instrumentation* John G. Webster,2006-04-07 The articles in The Encyclopedia of Medical Devices and Instrumentation focus on what is currently useful or is likely to be useful in future medicine They answer the question What are the branches of medicine and how does technology assist each of them Articles focus on the practice of medicine that is assisted by devices rather than including for example the use of drugs to treat disease The title is the only resource on the market dealing with the subject in encyclopedic detail Accessible to practitioners with a broad range of backgrounds from students to researchers and physicians Articles cover the latest developments such as nanotechnology fiber optics and signal processing

**Thesaurus of ERIC Descriptors** James E. Houston,2001-06-30 Researchers have come to rely on this thesaurus to locate precise terms from the controlled vocabulary used to index the ERIC database This the first print edition in more than 5 years contains a total of 10 773 vocabulary terms with 206 descriptors and 210 use references that are new to this edition A popular and widely used reference tool for sets of education related terms established and updated by ERIC lexicographers to assist searchers in defining narrowing and broadening their search strategies The Introduction to the Thesaurus contains helpful information about ERIC indexing rules deleted and invalid descriptors and useful parts of the descriptor entry such as

the date the term was added and the number of times it has been used *Thesaurus of ERIC Descriptors* Educational Resources Information Center (U.S.), James E. Houston, 1984 Thesaurus education includes a chapter on indexing and information retrieval methodology in the ERIC system References **Improving Accessibility and Usability of Medical Equipment for Patients with Disabilities** Martha Follette Story, 2008 *A Practicum for Biomedical Engineering and Technology Management Issues* Leslie R. Atles, 2008 **Vascular Ultrasound** Reinhard Kubale, Hubert Stiegler, Hans-Peter Weskott, 2023-07-05 An interdisciplinary guide to color duplex sonography organized by anatomic region The indications for vascular color duplex sonography CDS have expanded in recent years due to the availability of power Doppler B flow ultrasound contrast agents 3D reconstruction techniques and fusion with other imaging modalities CDS enables close interval follow ups after interventional procedures with improved prognoses Edited by Reinhard Kubale Hubert Stiegler and Hans Peter Weskott Vascular Color Duplex Ultrasound starts with the basic principles of diagnostic ultrasound physics and technology followed by invaluable tips on equipment settings possible artifacts and limitations hemodynamic essentials and the use of ultrasound contrast agents Subsequent chapters organized by anatomic region provide updated coverage on all peripheral and abdominal arterial and venous vascular regions microcirculation and tumor perfusion kidney and liver disease the use of contrast enhanced ultrasound CEUS in biliary intestinal splenic and pediatric diseases and novel future techniques Key Features Contributions from interdisciplinary experts in angiology neurology radiology vascular surgery gastroenterology nephrology phlebology rheumatology laser medicine and physics In depth guidance on examination techniques findings and potential pitfalls and how to avoid them A wealth of comparative CT MRI and angiography CDS images and 37 videos enhance understanding of impacted anatomy and the ability to master techniques and make accurate diagnoses This book includes complimentary access to a digital copy on <https://medone.thieme.com> Guide to the Evaluation of Educational Experiences in the Armed Services American Council on Education, 1988 **Thesaurus of Psychological Index Terms**, 2005 **Aerospace Medicine and Biology**, 1986 A selection of annotated references to unclassified reports and journal articles that were introduced into the NASA scientific and technical information system and announced in Scientific and technical aerospace reports STAR and International aerospace abstracts IAA **U.S. Government Research & Development Reports**, 1970

The Top Books of the Year Medical Device Use Error Analysis The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous compelling novels captivating the hearts of readers worldwide. Lets delve into the realm of popular books, exploring the captivating narratives that have charmed audiences this year. Medical Device Use Error Analysis : Colleen Hoovers "It Ends with Us" This poignant tale of love, loss, and resilience has captivated readers with its raw and emotional exploration of domestic abuse. Hoover masterfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can prevail. Medical Device Use Error Analysis : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This captivating historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids captivating storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Discover the Magic : Delia Owens "Where the Crawdads Sing" This captivating coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens crafts a tale of resilience, survival, and the transformative power of nature, captivating readers with its evocative prose and mesmerizing setting. These top-selling novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of engaging stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a exceptional and thrilling novel that will keep you guessing until the very end. The novel is a cautionary tale about the dangers of obsession and the power of evil.

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